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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/828,143	03/24/97	HSIA	H 24400-101

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HM22/0828

EXAMINER

MARX, I

ART UNIT

PAPER NUMBER

1651

*24*

DATE MAILED:

08/28/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

08/828,143

Applicant(s)

Hsia

Examiner

Irene Marx

Art Unit

1651



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Jul 9, 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 9-11 and 36-42 is/are pending in the application.
- 4a) Of the above, claim(s) 9-11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 36-42 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

The amendment filed 7/9/01 is acknowledged. Claims 36-42 are being considered on the merits. Claims 16-20 and 24-35 are cancelled. Claims 9-11 are withdrawn from consideration.

***Double Patenting***

Claims 36-42 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 15-24 of copending Application No. 08/879220. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in each of the applications are directed to substantially the same nutritional composition comprising bacteria, yeast and protein in certain overlapping ranges.

Therefore the claims are co-extensive.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant indicates that a terminal disclaimer may be filed. In the absence of this document, the rejection is repeated.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 36-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 36 is confusing in the recitation of "solid" with respect to the composition. It is unclear what is intended by "solid" in this context. For example, it is unclear whether the composition is intended without an internal cavity or not uninterrupted by a break or opening. Clarification is required. It is apparent from the specification that the material is granular or powdery.

Claim 36 and claims dependent thereon are confusing in the recitation of "*Lactobacilli*". It is unclear whether members of the genus "*Lactobacillus*" are intended or whether lactic acid bacteria in general are encompassed.

Claim 37 is confusing in the recitation of "genera or species" regarding the listing of species. In addition at least the species of *Lactobacillus* designated as "*germentum*", "*salvaroes*", "*fermetti*" do not exist. Correction is required.

Claim 40 lacks antecedent basis in claim 36 for "of the dry weight of the composition". Claim 40 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 39-42 are/remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

No basis or support is found in the present specification for the recitation of "dry" weight in claims 39-42. In the specification at page 9, lines 19-25 the percentage is based on the total mass of the mixture composition. No indication of dry or wet weight is found.

Therefore, this material raises the issue of new matter and should be deleted.

Applicants' arguments have been fully considered but they are not deemed to be persuasive.

Applicant mistakenly argues that the claims now recite "total mass". Claims 39-42 recite "dry weight".

Therefore the rejection is deemed proper and it is adhered to.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 36-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levy taken with Craig *et al.*, Prescott *et al.*, Jolly, Friend and El-Megeed *et al.*.

Levy discloses a nutritional or dietary composition comprising solid dried viable bacteria, dried, non-living yeast and concentrated protein (See, e.g., col. 2, lines 29-35). The viable *Bifidobacterium bifidus* bacteria, which constitute lactic acid bacteria (*Lactobacilli*?) constitute 10% of the composition, which is within the claimed range. In addition the composition comprises other lactic acid bacteria, which the translator interpreted as "lactic acid yeast". However, it is not clear that such a microorganism exists. It is submitted that the reference is directed to *Lactobacillus* or other lactic acid bacteria misnamed "levure", which can literally means "leavening" rather than "yeast". Even though the brewer's yeast component is indicated at a higher percentage than claimed herein, and the protein concentrate content is not explicitly disclosed, brewer's yeast constitutes a concentrated source of protein. One of ordinary skill in the art would presume that the composition comprising dried bacteria and yeast together stored as tablets as taught by Levy are in turn together stored in some sort of sealed, airtight container in the period after production and before consumption.

The reference differs from the claimed invention in the use of a concentrated soy, whey or animal protein. However, the use of protein concentrates in feeds or foods is old and well known in the art, as adequately demonstrated by Craig *et al.*, which disclose a composition comprising a concentrated protein such as dried whey or soy and an anti-scouring agent (See, e.g., bridging paragraph between col. 3 and 4 and col. 6, lines 49-62). The anti-scouring agent is disclosed to contain a probiotic such as *Lactobacillus*, which would be viable by definition, and, optionally, a

carrier such as dry yeast which would reasonably be expected to be non-living (See, e.g., col. 5, lines 16-27).

Prescott *et al.* is relied upon to demonstrate that the use of dried brewer's yeast and inactive dried baker's yeast in feed is old and well known in the art (See, e.g., pages 558-559).

In addition Jolly and Friend disclose the advantageous combination of whey and soy proteins with bacteria and/or yeasts for nutritional purposes. See, e.g., Friend, page 128; Jolly, col. 3, lines 15-35. Note, in particular, the discussion throughout Friend regarding the numerous benefits of providing *Lactobacillus* biomass for nutritional and therapeutic purposes. Jolly is cited to demonstrate that bacteria, yeasts and soy beans are all excellent sources of protein. (See, e.g., col. 3).

The references may differ from the claimed invention in process parameters such as concentration of bacteria, of yeast and/or of protein. However, the optimization of conditions identified as result-effective variables cited in the references would have been prima facie obvious to a person having ordinary skill in the art. The respective concentrations would have been adjusted by one of ordinary skill in the art depending on the particular application intended. See, e.g., El Megeed *et al.* col. 11 for teachings regarding adjustments on the concentration of bacteria, yeast and/or protein.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the composition of Levy by substituting the protein in yeast by protein in whey, for example, as suggested by Craig *et al.* and by adjusting the various parameters, such as the source and concentrations of bacteria, yeasts and protein, as suggested by the teachings of Jolly, Friend and El-Megeed *et al.*, in order provide well recognized dietary supplements, such as dried brewer's or baker's yeast, in combination with probiotics such as *Lactobacillus*, and concentrated sources of protein including soy and whey in a palatable form for the expected benefit of facilitating and maximizing the consumption of these valuable sources of nutrients.

Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of sufficient, clear and convincing evidence to the contrary.

Applicant's arguments as they pertain to the above rejection have been fully considered but they are not deemed to be persuasive.

Applicant argues that the references are incomplete and suffer from the fatal defect<sup>in</sup> that they fail to disclose a dry admixture of the components of the claimed compositions. While it is true that an anticipation rejection is no longer proper, this does not mean that one of ordinary skill in the art would not have been motivated to combine protein, yeast and *Lactobacillus* in dry form to provide a natural, nutritious composition in various proportions.

Even though the teachings of Jolly, Friend and El-Megeed *et al.* are directed to "wet" compositions (Response, pages 7-9), the teachings of Levy, and Craig *et al.* are directed to dry admixtures of nutrient and protein rich containing materials with *Lactobacillus* and yeast. The teachings of Prescott *et al.* are directed to the properties of dry admixtures of nutrient and protein rich containing dried yeast compositions. It would have been within the purview of the ordinary artisan in this art to combine well known dried protein concentrates with viable, dried *Lactobacillus* and surplus dried yeast, such as brewer's or baker's yeast, in various proportions to provide a food supplement composition, as suggested by the teachings of Prescott *et al.* and Levy.

It is noted that the compositions of claims 41 and 42 may contain 97 or 96% protein. Inasmuch as the minimum dry yeast concentration is 2.5% (Claim 36) or 3% (claim 40), it is apparent that the *Lactobacillus* component may be even less than the 0.1% required by claim 38. It is not apparent that the touted effectiveness of the composition is independent of the concentration of viable *Lactobacillus*.

The scope of the showing must be commensurate with the scope of claims to consider evidence probative of unexpected results, for example. In re Dill, 202 USPQ 805 (CCPA, 1979), In re Lindner 173 USPQ 356 (CCPA 1972), In re Hyson, 172 USPQ 399 (CCPA 1972), In re Boesch, 205 USPQ 215, (CCPA 1980), In re Grasselli, 218 USPQ 769 (Fed. Cir. 1983), In re Clemens, 206 USPQ 289 (CCPA 1980). It should be clear that the probative value of the data is not commensurate in scope with the degree of protection sought by the claim.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit since each is well known in the art for their claimed purpose and for the reasons outlined *supra*. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman*, 1943 C.D. 518. Applicants invention is predicated on an unexpected result, i.e. stability, an unpredictable phenomenon, highly dependent upon specific proportions and/or amounts of particular ingredients. Any mixture of the components embraced by the claims which does not exhibit an unexpected result is therefore *ipso facto* unpatentable.

Accordingly, the instant claims, in the range of proportions where no unexpected results are observed, would have been obvious to one of ordinary skill having the above cited references before him.

From the teachings of Levy, Craig *et al.*, Jolly, Friend and El-Megeed *et al.*, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Applicants have not demonstrated any unexpected properties of the compositions as claimed.

Therefore the rejection is deemed proper and it is adhered to.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Serial No. 08/828143  
Art Unit 1651

-8-

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (703) 308-2922.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The appropriate fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196 .



Irene Marx  
Primary Examiner  
Art Unit 1651